March 13, 2020

Submitted electronically to NCVHS@cdc.gov

William W. Stead, MD, Chair
National Committee on Vital and Health Statistics (NCVHS)
Centers for Disease Control and Prevention (CDC)
3311 Toledo Rd
Hyattsville, MA 20782-2002

Dear Dr. Stead:

PCMA appreciates the opportunity to provide comments regarding the change to the next named version of the NCPDP Telecommunication Standard.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and qualified health plans (QHPs) sold through the exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

Our comments are organized based upon the questions asked of industry stakeholders by NCVHS in February 2020. We hope that this input will assist the Committee in its discussions at its March 24-25 public meeting regarding the adoption of a new standard.

1. **What are the main enhancements between F2 and F6 that improve functionality of the standard? Please explain your response, and indicate why HHS should adopt version F6.**

The enhancements made include many that will result in increased transparency.

- F6 provides for more granular information on the prescription benefit and insurance structures through adjudicated program type information.
- Naming F6 as the new standard will improve the coordination of benefits information, allowing pharmacies and PBMs to have more detailed information on the parties involved in the adjudication process.

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- F6 will bring improvements to the information attached to controlled substance claims, including the quantity prescribed. This will allow distinguishing multiple dispensing events for a single fill, from true refills, as one example of increasing patient safety.
- The F6 standard allows for increased granularity of codified values. Added granularity will lead to greater automation of different processes for both the sender and the receiver of the transaction.
- F6 requires the inclusion information on intermediaries, notably Risk Evaluation and Mitigation Strategies (REMS) processors, which can streamline drug safety reporting requirements.
- Finally, F6 includes more specific fields to differentiate various types of fees, including taxes, regulatory fees, and medication administration fees.

Specifically, version F6 improvements over F4 that improve functionality include:

- F6 increases the dollar amount field length to support up to $999,999,999.99 will simplify coverage under prescription benefits of new innovative drug therapies, with prices that are beginning to exceed $1 million.
- By replacing free text clinical and non-clinical fields with codified entries, patient safety processes will be enhanced through enabling pharmacy and prescriber system automation and interoperability of clinical information.
- IT development, testing and implementation burdens are reduced. This is a result of eliminating intermediary qualified message solutions in prior versions and enhancing the use of the Other Related Benefit Information segment. Examples include Medicare-Medicaid dual eligibility status identifiers, end-stage renal disease and hospice indicators and dates, formulary alternative effective date, and provider validation data sources (e.g. OIG exclusion files, Medicaid enrollment files, Medicare Part D precluded prescribers).
- Patient access to care is expedited through workflow interoperability between the PBM, pharmacy, and prescriber, as a result of new response data elements to better communicate current and future effective date plan formulary alternative information and patient cost share amounts.

Why F6 should be adopted:

NCPDP Telecommunication Standard F6 offers enhancements that better support current and future business needs in the following areas:

- Improves structure to support clinical evaluation of prescription products and plan benefit transparency which are key components in achieving expected healthcare outcomes related to value-based care, digital therapeutics, social determinants of health, and other areas of healthcare innovation.
- Adds opportunities for system automation, harmonization of data, and workflow interoperability across the care continuum, which will expedite patient access to prescribed drugs.

- Enhances drug utilization/patient safety mechanisms to provide better tools to address health issues.
- Facilitates patient care coordination across distinct components of prescription and medical benefits.
- Expedites claim resolution through improved data analytics.
- Allows adjudication of claims for innovative drug therapies using industry standard processes leveraging expanded financial fields.

2. **When should HHS adopt and require implementation of F6? If the proposed timelines are not met, what operational and/or technical actions do you recommend industry take to adjust to the issues the updated version(s) of the standards were intended to address? What is industry's desired implementation timeframe? Why?**

A key concern with any industry-wide implementation is the timing and effort, especially for entities that traditionally have more difficulties in these transitions. Historically, small, independent pharmacies and state health programs have the most difficulty. For this reason, we support the timeline recommended by NCPDP (reproduced below).

The NCPDP timeline calls for the final rule to be published no later than August 2021, with implementation occurring no later than May 2025. This timeline allows enough time for all parties to prepare properly , while limiting the amount of time for the majority of organizations to incur extra costs for efforts such as dual version transaction support, double development and testing efforts for such transition periods, and the unique processes required to support a transition period with two concurrent transaction versions. The use of a date other than January 1 minimizes any complications that might arise with other changes to benefits and processes that typically occur early in the year. The extension of the industry timeline beyond three to four years after the final rule publication will increase costs for the majority, while realizing a diminished return in accommodating those entities that are slower to implement. The NCPDP timeline also considers the general tempo of claim processing, including the impact of benefit renewal dates and support for flu season. This timeline will influence the overall cost of implementation. A longer timeline will not only incur the additional costs but also project start and stops such as those experienced during the D.0 and ICD-10 implementations due to the extensions of the regulatory compliance dates.

If the Final Rule is not published in the recommended timeframe, industry will need to continue using NCPDP Version D.0 and the associated work-arounds including manual claims processing, splitting of claims for million-dollar drugs and manual workflow steps to identify and act upon patient safety alerts. Other features and their related benefits such as information on future formulary changes will simply not be available to trading partners and patients.

Recommended timeline for F6 implementation:

Step #	Milestone	F6 Timeline
1	NCVHS hearings completed	4/1/2020
2	HHS releases NPRM	12/31/2020
3	NPRM comment period ends	02/28/2021
4	Final Rule is published	08/28/2021
5	IT business planning, development, informal and formal testing	
6	Trading partner certification, pilot use in production environment	
7	NCPDP recommended full use of version F6	08/28/2024
8	HHS Compliance Date	05/01/2025

3. **We understand version F6 has been updated to accommodate high cost medications, in addition to several other changes. How will industry accommodate these medications until the standard is officially adopted for use?**

Manual workarounds will continue to be used including paper billing or the splitting of claims. We request clarification on how the PDE and Medicaid Encounter reporting processes will be modified to support the use of the expanded dollar fields once the standard is adopted.

4. **What is the latest date the standard must be officially available for use? What is industry's deadline for adoption?**

PCMA is currently not aware of a hard date in which F6 must be officially available for use, as the industry is supporting alternative solutions to address the new business cases. However, the health care industry is rapidly changing where business needs and regulatory requirements could quickly necessitate the implementation of enhancements in F6. PCMA recommends the timeline outlined above be supported by HHS and communicated as soon as possible, to allow stakeholders to begin budgeting, planning, development work, and coordinating the necessary trading partner agreements.

5. **Are there any known barriers to implementing NCPDP version F6? If so, what are they and what parts of industry do they affect?**

The barriers around implementation relate to associated processes, such as PDE and Medicaid Encounter reporting. We seek guidance from CMS as to when and how these processes will be updated so as to reflect the enhancements made to the NCPDP Telecommunication Standard.

Other barriers are those related to readiness, such as state Medicaid plans or smaller entities that may have financial constraints that impede implementation efforts. Also of concern are compliance dates that may coincide with annual enrollment periods (e.g. January and July) or flu season (increased immunizations).

6. **Please provide any qualitative or quantitative data that depict the costs and benefits of implementing NCPDP version F6.**

We have provided a qualitative list of benefits in response to question 1 above. At this time we are unable to fully quantify the costs of this transition on our members, but we intend to provide substantive comments on the administrative costs of the transition to HHS in response to their future proposed rulemaking.

7. **Are you aware of any testing that has taken place with the NCPDP Version F6 standard between trading partners, and the outcome of that testing? If no testing has taken place, what testing strategy should take place in advance of the implementation date?**

PCMA is not aware of any such testing. Trading partners typically wait for the final rule to begin testing due to the level of investment and effort required. PCMA recommends the NCPDP SNIP Process for testing strategy be followed. Additional testing strategies should be evaluated to ensure that downstream reporting, such as PDE and Medicaid Encounter processes are fully vetted.

On the related topic of the use of the batch standard and subrogation guide, PCMA requests NCVHS remind HHS that the following DSMO Requests should be included in the NPRM and Final Rule as they would leverage the NCPDP Telecommunication Standard F6:

a. DSMO 1201 requests the Batch Standard v15 be named under HIPAA.
b. DSMO 1202 requests the Subrogation Implementation Guide for Batch Standard v10 be named in HIPAA for Medicaid use to replace the Medicaid Subrogation Standard Implementation Guide, version 3.0.

Conclusion

We appreciate the opportunity to provide comments to NCVHS in support of the adoption of the NCPDP F6 telecommunications standard. If you need additional information, please contact me at tdube@pcmanet.org.

Sincerely,

Tim Dube
Assistant Vice President, Regulatory Affairs

cc: Wendy Krasner, Senior Vice President, Regulatory Affairs, PCMA
Sharon Arnold, Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy